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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,470	03/11/2004	Daniel H. Teitelbaum	UM-08764	7421

7590 07/21/2006

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,470	TEITELBAUM ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5-10-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment filed May 10, 2006 is acknowledged. Amendments to the specification on page 3 are noted. Claims 6 and 8-17 are canceled. New claims 18-21 are presented. Accordingly, claims 1-5, 7 and 18-21 are now under consideration.

An Information Disclosure Statement filed May 10, 2006 is further acknowledged. The references have been reviewed to the extent each has been supplied.

Claims 18 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 18 and 21 recite the limitation "colitis". There is insufficient antecedent basis for this limitation in independent claim 1 from which they depend.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 211 USPQ 323. Applicants refer to the specification at page 8, lines 1-6, for support for new claim 20. A review of this portion of the specification fails to disclose a recitation directed to prevention of body weight loss.

Subsequent to the cancellation of claims 8-15, the rejection set forth in the last Office Action under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention, is moot.

Applicants' arguments with respect to the rejection of claims 1-17 under 35 U.S.C. 102(e), as being anticipated by Rodgers et al., U.S. Patent 6,821,953, and to the rejection of claims 1-6, 8-14, 16 and 17 under 35 U.S.C. 102(b), as being anticipated by Acton et al., U.S. Patent 6,632,830, set forth in the last Office Action, have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodgers et al., U.S. Patent 6,821,953, in view of The Merck Index.

Rodgers teaches the administration of angiotensin converting enzyme (ACE) inhibitors along with a peptide fragment in various inflammatory conditions of the bowel, such as ulcerative colitis. See claim 11, as well as column 3, lines 4-25, where examples of angiotensin converting enzyme inhibitors are disclosed, as required by instant claim 7. The open language of the present claims allows for the inclusion of any number of additional active agents in the claimed methods. See column 9, line 59, through column 10, line 7, where modes of administration are disclosed, as required by instant claims 4 and 5. The claims differ in that Rodgers fails to describe a reduction in the characteristics that define an inflammatory bowel disease, such as histological

parameters, the presence of heme positive stools, weight loss and clinical severity of colitis. However, the qualitative and quantitative determinations of such characteristics are conventionally examined when a practitioner skilled in the art of gastroenterology ascertains the progression of an inflammatory bowel disease. The **Inflammatory Bowel Diseases** section of the The Merck Index establishes that weight loss, histological parameters, heme positive stools and clinical symptoms are routinely followed in patients having inflammatory bowel diseases. See, in particular, the sections describing Pathology and Symptoms, Signs and Complications. A reference may be applied for all it teaches or suggests to one of ordinary skill in the gastroenterology art. In view of the combined teachings of Rodgers and The Merck Index, it would have been reasonable to expect a reduction in the severity of an inflammatory bowel disease following the administration of an ACE inhibitor, optionally in combination with another active agent.

Claims 1-5 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acton et al., U.S. Patent 6,632,830, in view of The Merck Index.

Acton teaches the administration of an angiotensin converting enzyme (ACE) inhibitor in the treatment of an inflammatory bowel disease. See column 36, lines 60-61, as well as column 37, lines 12-23, and columns 41-43, where modes of administration are disclosed. The claims differ in that Acton fails to describe a reduction in the characteristics that define an inflammatory bowel disease, such as histological parameters, the presence of heme positive stools, weight loss and clinical severity of

colitis. However, the qualitative and quantitative determinations of such characteristics are conventionally examined when a practitioner skilled in the art of gastroenterology ascertains the progression of an inflammatory bowel disease. The **Inflammatory Bowel Diseases** section of the The Merck Index establishes that weight loss, histological parameters, heme positive stools and clinical symptoms are routinely followed in patients having inflammatory bowel diseases. See, in particular, the sections describing Pathology and Symptoms, Signs and Complications. A reference may be applied for all it teaches or suggests to one of ordinary skill in the gastroenterology art. In view of the combined teachings of Acton and The Merck Index, it would have been reasonable to expect a reduction in the severity of an inflammatory bowel disease following the administration of an ACE inhibitor.

In the last Office Action claims 1-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Studdy et al., Lancet (abstract), particularly in view of Rao et al., Indian Journal of Pharmacology (abstract). It was asserted Studdy teaches the elevation of serum angiotensin-converting enzyme activity in patients with inflammatory bowel disease. Based on the abstract alone, it appears the inflammatory bowel disease, enteritis, is exemplified. Further, based on the abstract alone, the administration of angiotensin-converting enzyme inhibitors is suggested as a treatment. Motivation is provided to administer an angiotensin-converting enzyme inhibitor based on the teachings of Rao wherein the administration of the angiotensin-converting

enzyme inhibitor, captopril, proved to be effective in causing a significant reduction in ulcer index, an inflammatory characterization of stomach ulcer.

Upon reconsideration, the rejection of record under 35 U.S.C. 103 is withdrawn. The Rao reference is directed to stomach, not bowel, inflammation.

No claim is allowed.

Robinson et al., US 2004/0266831, Hadida-Ruah et al., US 2004/0266758 and Hallberg et al., WO 2004/085420, are cited to show further the state of the art.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

July 16, 2006 Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER